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CROSS-CULTURAL VALIDATION OF THE PEDIATRIC QUALITY OF LIFE INVENTORY™ 3.0 CARDIAC MODULE ARABIC LANGUAGE

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ABSTRACT

Background

Health -related quality of life had gained a major interest among researchers as a health outcome for all age groups, therefore, many scale had been developed to measure it. Pediatric Quality of Life Inventory™ 3.0 Cardiac Module is widely used measure and it has been translated into many languages

Aim

This study describes the process of translating this scale into the Arabic language, and to test its psychometric properties for cross-cultural validation.

Methods

The scale was translated from English to Arabic and back-translated through a panel of experts. The Arabic version was administered to healthy children and those with Congenital Heart Defects in Jordan. Statistical methods were used to test the psychometric properties of the Arabic version of the PedsQL (3.0) Cardiac Module and its ability to discriminate between children in the mentioned groups.

Results

Cronbach's alpha coefficients for child self- and parent proxy-reports exceeded 0.6 for all subscale and total scale scores for the pre-test and post-test except for the perceived physical appearance of the child self-report pre-test form and the total score of the Parents' Proxy-scores Post-test form. Testing for discriminant validity showed that children and adolescents with congenital heart defects had a lower health- related quality of life than the healthy (control) group. Children and adolescents with congenital heart defect scores were lower in all domains of the PedsQL (3.0) Cardiac Module.

Conclusions

Initial testing of the Arabic version of the Peds QL (3.0) Cardiac Module suggests that the scale has good psychometric properties.

INTRODUCTION

Background

The world's prevalence of Congenital Heart Defects (CHD) among infants is from 3.7 to 17.5 per 1,000, which form 30-45% of all congenital defects [1]. According to the Centers for Disease Control and Prevention (CDC) around 40000 babies are born with CHD every year in the United States [2]. The expansion of diagnostic studies such as echocardiography, cardiac catheterization and the advancements in cardiac surgeries, increased the survival rate among the children and adolescents diagnosed with CHD [3, 4].

The increased survival rates through childhood and adolescence have an impact on their well-being as it is involved with reduced physical, social or psychological functioning [4, 5]. As a consequence, this has an impact on different health outcomes such as Health -Related Quality of Life (HRQoL) [6]. Despite the advanced treatment strategies and technologies in the field of cardiology and cardiac surgeries; children and adolescents diagnosed with CHD are still at risk for disturbed physical, psychosocial, cognitive and emotional functioning. Moreover, complications of impaired Quality of Life (QoL) may lead to decrease in school achievement related to absenteeism from school caused by recurrent hospitalization, or impaired physical functioning [4]. Almost 1.5 million births are born with CHD around the world annually, 85% of them are reaching the adulthood [7]. The impact of such fact on their health, quality of life, psychological well- being and their social relationships emphasizes the necessity for exploring the impact of those structural defects on the HRQoL.

Overall quality of life of children and adolescents integrates more than just medical and treatment aspects of the individual's life, rather it includes issues regarding their role in life for children as being school students, the social role with their friends, communication, cognitive, and physical abilities. Therefore, HRQoL was defined as a "subjective, individual, multidimensional construct, denoting to that measure of the quality of life which is concomitant with health, and addresses personal awareness of physical, emotional, and social functioning and well-being" [8]. Researchers are concerned to understand the subjective perception of children and adolescents, this will aid in gaining knowledge about their HRQoL [9]. This has led to increased number of measures that helped in assessing the HRQoL among children from different age groups and different health conditions. One of those measures is the Pediatric Quality of Life Inventory [TM] 3.0 Cardiac Module. This measure has been widely used in Europe and the western cultures and it has been translated into several languages [10-12]. This paper describes a study to translate the Pediatric Quality of Life Inventory [TM] 3.0 Cardiac Module English into Arabic and to assess the reliability and validity of the new Arabic version for cross-cultural validation. The translation was conducted as part of an investigation into the HRQoL of children and adolescents with CHD in Jordan.

Aim

This paper has three aims: first, to explain the process of translating PedsQL.^{TM} 3.0 Cardiac Module self- and proxy-reports for the ages 8–12 and 13–18, from English into Arabic; second, to assess the reliability of the new Arabic version of the scale, and third, to assess its validity for cross-cultural validation.

Methods

Measures

The PedsQL^{TM} is a group of measures that depend on a modular system that measures HRQoL in pediatrics from different age groups in which each age group has a specific measurement that would take into consideration the cognitive and physical development differences for each age group. This model,which was developed by Professor James Varni; is used to assess the HRQoL in children and adolescents who are healthy and those who had an acute or chronic health condition [10].

The Child and Parent Reports of the PedsQL.^{TM} 3.0 Cardiac Module for Children (ages 8-12), and adolescents (ages 13-18); is composed of 27 items comprising six dimensions related to Heart Problems and Treatment (seven items). The Treatment II (five items), perceived physical appearance (three items), treatment anxiety (four items), cognitive problems (five items), and communication (three items) for child self-report ages 8–18 years and parent proxy-report in all age groups. Parent-proxy-reports concerned with parent's perception of their child's

HRQOL. The items for each of the forms are basically identical, but the language differs in developmentally appropriate wording and the use of the first or third person for child self-report or parent proxy-report, respectively.

The instructions for scoring of the PedsQL. TM 3.0 Cardiac Module ask how much of a problem indicated in each item has been during the past month. A 5-point Likert scale is used across child self-report for ages 8 to 18 years and parent proxy report from 0= never a problem to 4= almost always a problem). Each item is then reverse scored and linearly transformed to a 0–100 scale so that higher scores indicate a better HRQoL.

The items are reverse-scored and linearly transformed to a scale from zero to 100 points (0=100, 1=75, 2=50, 3=25, and 4=0). To create scale scores, the mean is computed as the sum of the items over the number of items answered (this includes missing data). If more than 50% of the items in the scale were missing, the Scale Score is not computed. Imputing the mean of the completed items on a scale when 50% or more are completed is generally the most unbiased and precise method.

Translation Process

The translation process from US English language to the Arabic language took place through several steps as was instructed by the Mapi Research Institute linguistic validation of the PedsQoL Guidelines for the crosscultural research. The linguistic validation of a QoL questionnaire should consist of at least 3 steps: forward translation, backward translation, and patient testing [13].

Forward Translation

The PedsQoL Cardiac Module 3.0 for the ages 8-12 and 13-18 were translated into Arabic by two bilingual experts, where each one of them first produced a draft of the translated instruments. Each one has independently produced a version of the items, instructions and the response choices, then the two versions were compared and a final version of

the instruments was produced. This intermediate version was then reviewed by a pediatric cardiologist who is fluent in English and whose mother tongue is Arabic. A final version of the instruments was then produced. The Arabic version was revised by a committee that consists of three members and validated the words and grammar structure of the items.

Backward Translation

Backward translation from Arabic to English has been done blindly by a third bilingual expert. This mean, that translation of the Arabic version has been done without having an access to the original English version. The original English version and the newly produced an English version were compared by the researcher and the translator.

Some expressions which had been used in the original English version was differently expressed in the backward translation version. For the translator, he used different words, but it produces semantically same meaning in Arabic as the expressions in the original English version. Such as "I get out of breath when playing sports" which, when back translation done, the expression of "I have difficulty breathing when I play sport" was used.

Furthermore, in the original version, the word chest tightness was replaced with discomfort and pain as it was literally translated from the produced Arabic version, which means the same in the Arabic language for "my chest hurts or feels tight" in the original English version.

This was found also in the expression of "I wake up at night with difficulty breathing" in the backward translated version, as it was "I wake up at night with trouble breathing" in the original version. And in the expression "I need to rest more than my friends" which was "I have to rest more than my friends". Those differences don't change the original conceptual meaning of the words. So it was agreed upon by the researcher and the translator.

Patient Testing

The last phase on the process was patient testing. Cognitive interviews were conducted with five patients and their parents from each age group, the children's group (8-12) and teen group (13-18). During the interviews, the forward translated Arabic version was administered and the participants were interviewed for the child self-report forms and their parents for the parents' proxy-report forms; the participants and parent interviews took place separately. All participants and their parents were native speakers of Arabic language, and from different areas in Jordan as there are different dialects in the north, middle and south Jordan to ensure cultural validation of the developed Arabic version of the measurement.

From the child age group: two children were 8 years old, one was 9 years old, and two were 10 years old. Three boys and two girls. From the teens' age group: there were 13, 14, 15and two were 17 years old. They were three boys and two girls too. The interview was face to face with each participant, an introduction and explanation were introduced to the participants. Then they were asked to complete the questionnaire. During this time they were asked if they had any question or inquiry regarding the items, or if there anything needs to be explained or clarified more.

The teens needed 15 minutes to complete the measurement. On the other hand, young children needed 20 minutes to read and to complete. Only one child asked about the item "I feel worried how the medicine affects my body" an explanation was giventowhether she was afraid that taking medicine will change her body. Parents completed the questionnaire in 10 minutes, no clarification was asked in regards to the items.

Procedure

Participants and Settings

The Arabic version of the PedsQoL Cardiac Module 3.0 was developed and tested for reliability and validity using data collected from 227 children and adolescents with CHD and their parents recruited from the pediatric cardiology clinics in Queen Alia Heart Institute (QAHI) at the Royal Medical Services (RMS). The participants aged from 8 to 18. One hundred and twenty two of the participants were females (54%) and 105 were males (46 %).

To assess the reliability, the Arabic version of the scale was administered twice to each participant with an interval of two weeks, where they were given a follow up appointment at the pediatric cardiology clinics. Children and adolescents completed the questionnaires in a separate room from their parents at the clinics. For the purposes of discriminant validity testing, the known group method was used, where a separate group of154 healthy child was included; those children and adolescents were with their siblings during their visits at the clinics. The group aged from 8 to 18, 84 were males (54.5 %) and 70 (45.5%) were females. Table one summarizes the characteristics of the children and adolescents involved in the study.

Table 1: Demographic Characteristics of the Study Sample

Study Groups	Age Groups (Years)	Gender Male (%) Female (%)	Diagnosis
Healthy N= 154	8-18	84 (54.5) 70 (45.5)	Healthy
CHD N= 227	8-18	105(46) 122(64)	Ventricular Septal Defect (VSD) = 59 (26%) Pulmonary Stenosis (PS) =30 (13.2%) Transposition of Great Vessels (TGV) = 31 (13.7%) Coarctation= 30 (13.2%) Tetralogy of Fallot (TOF) = 47 (20.7%) Dextrocardia = 14 (6.2%) Aortic Stenosis (AS) = 15 (6.6%) Tricuspid Atrasia = 1 (.4%)

Several steps were carried out to guarantee protection of participants. The approval from the ethical committee at the School of Nursing at the University of Jordan was obtained. Moreover, the approval of the IRB at the Royal Medical Services (RMS) was obtained prior to conducting this study. The purpose of the study and data collection process was explained to the nursing director, head chief of the Pediatric Cardiology and head chief of the Pediatric Cardiac Surgery Departments in QAHI to facilitate data collection.

This study was performed in accordance with ethical standards, as described in the Belmont Report, which articulated three essential ethical principles that form the basis for standards of the ethical conduct in research. Those primary principles are beneficent, respect for human dignity, and justice [14].

Parents were asked to sign an informed consent form after explaining the purpose of the study. Moreover, an assent was obtained from children and adolescents as a gesture of respect for their autonomy. The right to privacy was protected by ensuring the participant confidentiality through taking several steps. An identification code number was used and placed on each questionnaire package. All related data that identify the participants were kept in a lockedcabinet in a secured location. Only the researchers had an access to the data collected only for the research purpose. Data will be destroyed after data analysis and the publication of the study results or when it is practical doing that.

Statistical Analysis

Internal consistency, reliability was determined using Cronbach's alpha coefficient. A result of Cronbach's alpha coefficient from 0.6–0.7 represents an acceptable reliability and 0.8 or higher represents good reliability [15]. Spearman's *p* was used to assess the agreement between child-reports and parents' proxy-reports (with levels for medium and large correlation at 0.30 and 0.50, respectively). In order to assess the stability over time, the Spearman's *p* was used to detect the correlation of test and retest scores for children's self-reports and parents' self-reports.

Construct validity was determined using the known group method, and to test the fairness and stability of the measurement by comparing between the median; it was preferable to use the Mann-Whitney U as a nonparametric test to detect difference in HRQoL between the CHD group and the healthy group. Face and content validity were assessed by three experts; two pediatric cardiologists and one registered nurse who works in a pediatric cardiac critical care unit.

RESULTS

Internal Consistency

Cronbach alpha coefficients for child self-report and parent proxy-reports are summarized in Table 2. Internal reliability coefficients exceeded 0.6 for all PedsQoL Cardiac Module 3.0 in both children's and adolescents' self-reports and parents-proxy in all sub scale' scores, except for the pre-test Perceived Physical Appearance module for the child self-report which was 0.43, and the total score of the Parents' Proxy-scores Post-test form.

The highest was the Heart Problems and Treatment child self-report post-test form. Moreover the total scale scores with high Cronbach alpha score of 0.91 for the post test Child self-report total scale.

Table 2: Cronbach's Alpha Coefficients for the PedsQL.^{TM} 3.0 Cardiac Module (Arabic Version) for Both the Children and the Parents

Pedsql.^{TM} 3.0 Cardiac Module (Arabic Version)	No. of Items	Child Self-Reports		Parents' Proxy-Reports	
		Pre-Test	Post-Test	Pre-Test	Post-Test
Heart Problems And Treatment	7	0.87	0.93	0.87	0.64
The Treatment II	5	0.90	0.75	0.93	0.93
Perceived Physical Appearance	3	0.43	0.69	0.73	0.73
Treatment Anxiety	4	0.76	0.63	0.85	0.85
Cognitive Problems	5	0.72	0.74	0.72	0.72
Communication	3	0.85	0.83	0.83	0.83
Total Scale score	**6**	**0.88**	**0.91**	**0.73**	**0.5**

Parent-Child Agreement

Correlations of test-retest scores of children self-reports and parents-proxy reports are in Table 3. Correlations ranged from 0.152 for the post-test Treatment Anxiety scale, to 0.852 for the pretest Heart Problems and Treatment scale. Pretest and post-test correlations are also presented in Table 3. Significant correlations ranged from the high correlation of 0.712for the Communication scale to low correlation of 0.341for the Treatment Anxiety scale, and 0.739 for the Total Scale score.

Table 3: Reliability of the PedsQL.^{TM} 3.0 Cardiac Module (Arabic Version) – Temporal Stability

Correlation between Child and Parent form			Stability Over Time
Pedsql.^{TM} 3.0 Cardiac Module (Arabic Version)	**Pre-Test**	**Post-Test**	**Pre-Test Post-Test**
Heart Problems And Treatment	0.852**	0. 700**	0.604**
The Treatment II	0.025	0.107	0.545**
Perceived Physical Appearance	0.025	1.000**	0.443**
Treatment Anxiety	0.215**	0.152*	0.341**
Cognitive Problems	0.489**	0.186**	0.704**
Communication	0.032	0.400**	0.712**
Total Scale score	**0.215****	**0.409****	**0.739****

** Correlation is significant at the 0.01 level (2-tailed).

*Correlation is significant at the 0.05 level (2-tailed).

Discriminant validity testing results in which score differences between the CHD group and the healthy group were calculated. As summarized in Table 4. Mann-Whitney U test results showed that HRQoL of children and adolescents with CHD scores were significantly lower (*Mdn* = 2) than scores of children and adolescents in the healthy group (*Mdn* = 4), *U* =2266.0, *p* =<.001,*Z* = 14.3. Moreover, Mann-Whitney U test results showed that children and adolescents with CHD scores on all subscales of the PedsQL.^{TM} 3.0 Cardiac Module were significantly lower than healthy children and adolescents.

Face and content validity, which were determined by a panel of experts approved the current developed Arabic version of the PedsQL.^{TM} 3.0 Cardiac Module. In order to unify the entire scale format, the template of the original English scale was used for the current development version as directed by the MAPI research institute.

Table 4: Mann-Whitney U Test for Discriminant Validity Testing between CHD and the Healthy Group

Mann-Whitney U test					
CHD(N= 227)		Healthy(N= 154)			
Pedsql.^{TM} 3.0 Cardiac Module (Arabic Version)	**Median**	**Median**	*U*	*P*	*z*
Heart Problems And Treatment	2	3	3185	.001*	14.288
The Treatment II	2	3	6339	.001*	10.92
Perceived Physical Appearance	2	3	6339	.001*	10.92
Treatment Anxiety	2	3	1270 6	.001*	-4.698
Cognitive Problems	2	3	1137 3	.001*	-5.987
Communication	2	3	9266	.001*	-8.613
Total Scale score	2	4	2266	.001*	-14.807

* Likelihood of association is significant at <0.01 level (2-tailed).

DISCUSSIONS

This study describes the process of translating the PedsQL.^{TM} 3.0 Cardiac Module to Arabic language and testing the reliability and validity of the produced Arabic version. The findings generally support the reliability and validity of the Arabic translation of the cardiac-specific instrument to assess HRQoL of Jordanian children 8-18 years of age with CHD.

The results of the internal consistency reliability were accepted in all self-report and proxy-report versions for both children and adolescents age groups. The Cronbach's alpha results of each scale of the PedsQL.^{TM} 3.0 Cardiac Module for self-reports and parents' proxy-reports forms were high. Those results are consistent with previous findings [11, 12, 16, 17]. All sub-scales showed an acceptable high value except in the Perceived Physical Appearance in child self-report pretest form, this was consistent with results in Berkes, et al., study [11].

However,the Cronbach alpha coefficient result increased in the post-test scores; this may be due to recall bias as the scales were administered in a two week period.

Construct validity of the PedsQL.^{TM} 3.0 Cardiac Module was tested where agreement between children self-reports and parents' proxy-reports results were generally moderate to good. Those results were significant in all subscales except for the Treatment II scale in the pre-test and post-test forms, the Perceived Physical Appearance of the pre-test form, and the Communication scale pre-test form in child self-reports. The low correlation results are consistent with findings in other studies [11, 12] those results may be due to internalization of feelings in these age groups, that their perception of physical appearance would be important for them in a way that their parents don't realize and in turn would affect how they communicate their concerns.

The PedsQL.^{TM} 3.0 Cardiac Module indicated better HRQoL for healthy children and adolescent group than in children and adolescents with the CHD group which supports the construct validity of the Arabic version of the instrument and its ability to discriminate between healthy and CHD groups, this is similar to the finding in several studies [11, 17].

CONCLUSIONS

The translation of the PedsQL^{TM} 3.0 Cardiac Module to Arabic language adds to the body of knowledge by further understanding the impact of the CHD as a chronic condition in children and adolescents. Psychometric properties of the produced Arabic version show favorable results that support the reliability and the validity of the instrument.

LIMITATIONS

Children and adolescents with different chronic health conditions were not included as a known group method to assess discriminant validity. Recommendations for future testing of the discriminant construct validity in which participants with different chronic health conditions to further test the instrument's ability to discriminate between the children and adolescents' HRQoL with CHD and other chronic conditions. Furthermore, testing the construct validity of the instrument with the PedsQoL generic scale is recommended.

Declarations

Ethical approval: this article does not contain any studies with human participants performed by any of the authors.

Competing Interests

Dr. Varni holds the copyright and the trademark for the PedsQL™ and receives financial compensation from the Mapi Research Trust, which is a nonprofit research institute that charge distribution fees to for-profit companies that use the Pediatric Quality of Life Inventory™. The PedsQL™ is available at the PedsQL™ website [18].

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Conflict of Interest: The authors declare that they have no conflict of interest.

Consent Form: a signed informed consent had been obtained from all participants prior to filling the questionnaires.

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